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Page 1
      IN THE UNITED STATES DISTRICT COURT
   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
             CHARLESTON DIVISION
IN RE: ETHICON, INC.,
                        ) MASTER FILE NO.
PELVIC REPAIR SYSTEM
                       )2:12-MD-02327
PRODUCTS LIABILITY
LITIGATION
                        )MDL 2327
Joy Essman
                        )IN RE TVT & TVT-O
Case No. 2:12-cv-00277
Barbara A. Hill
                        ) JOSEPH R. GOODWIN
Case No. 2:12-cv-00806
                        )U.S. DISTRICT JUDGE
Paula Kriz
Case No. 2:12-cv-00938
                         ) DEPOSITION OF
                         ) CHRISTINA PRAMUDJI, M.D.
Brenda Riddell
Case No. 2:12-cv-00547
Sharon Carpenter
Case No. 2:12-cv-00554
Mary Jane Olsen
Case No. 2:12-cv-00470
                         )MARCH 24, 2016
Virginia White
Case No. 2:12-cv-00958
Sandra Wolfe
Case No. 2:12-cv-00335
Marie Smith (f/k/a Banks))
Case No. 2:12-cv-01318
Sherry Fox
Case No. 2:12-cv-00878
Lois Durham
Case No. 2:12-cv-00760
Elizabeth Blynn Wilson
Case No. 2:12-cv-01286
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Page 2
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       Case No. 2:12-cv-00401 )
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                                                        Page 3
                                                                                                                                Page 5
                                                                                APPEARANCES:
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                Thursday, March 24, 2016
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                                                                         4
                                                                                      Suite 1400
                                                                                      Ridgeland, Mississippi 39157
  4
                                                                         5
                                                                                      (601) 948-5711
  5
                  Oral Deposition of CHRISTINA
                                                                                      Counsel for Defendants
  6
        PRAMUDJI, M.D., In Re TVT and TVT-O, taken
                                                                         6
  7
        pursuant to notice, was held at the Westin
  8
        Houston, Memorial City, 945 Gessner Road,
                                                                         7
  9
        Houston, Texas, beginning at 11:10 a.m., on
                                                                         8
10
        the above date, before Micheal A. Johnson,
                                                                         9
11
        Registered Diplomate Reporter, Certified
                                                                       10
12
        Realtime Reporter, and Notary Public for the
                                                                       11
                                                                       12
13
        State of Texas.
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1	INDEX	1	PROCEEDINGS
	CHRISTINA PRAMUDJI, M.D.	2	
2	March 24, 2016		CHRISTINA PRAMUDJI, M.D.,
3	Water 24, 2010	3	having been first duly sworn,
4	APPEARANCES 4	4	testified as follows:
5	AFFEARANCES 4	5	EXAMINATION
	EVAMINATION OF CUDICTINA DDAMUDU M.D.		Y MR. FAES:
6	EXAMINATION OF CHRISTINA PRAMUDJI, M.D.:	7	Q. Doctor, my name is Andy Faes,
7	BY MR. FAES 8	8 an	d I'm here to take your deposition now
8	BY MR. GAGE 66	9 re	garding the TVT and TVT-O case. Do you
9	BY MR. FAES 68	10 un	derstand that?
10		11	A. Yes.
11	CERTIFICATE 69	12	Q. You understand that you're
12	ERRATA 71		Il under oath from earlier and you're
13	ACKNOWLEDGMENT OF DEPONENT 72		ll sworn to tell the truth, correct?
14	LAWYER'S NOTES 73	15	A. Yes.
15		16	
16			Q. And again, as before, if I ask
17			question that doesn't make sense to you,
18		_	ease let me know and I'll try to rephrase
19			e question.
20		20	A. Okay.
21		21	MR. FAES: I'm just going to
22		22	continue the exhibit numbers. Is that
23		23	okay?
24		24	MR. GAGE: That's fine.
	Page 7		Page 9
1	DEPOSITION EXHIBITS	1	(Deposition Exhibit 18 marked.)
	CHRISTINA PRAMUDJI, M.D.	2 B	Y MR. FAES:
2 3	March 24, 2016 NUMBER DESCRIPTION MARKED	2	O Dantan Ilmanina ta bandana
4		3	O. Doctor, I'm going to nand you
	Exhibit 18 Expert Report of 9	3 4 wl	Q. Doctor, I'm going to hand you hat's been marked as Exhibit No. 18 to your
1	Exhibit 18 Expert Report of 9 Christina Pramudii, M.D.	4 wl	hat's been marked as Exhibit No. 18 to your
5	Exhibit 18 Expert Report of 9 Christina Pramudji, M.D.	4 wl 5 de	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?
5	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14	4 wl 5 de 6	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the
5 6	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji	4 wl 5 de 6 7	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're
5 6 7	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34	4 wl 5 de 6 7 8	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he
5 6	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34 Exhibit 21 Gynecare TVT 43	4 wl 5 de 6 7 8	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he means we're continuing the exhibit
5 6 7	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34 Exhibit 21 Gynecare TVT 43 Tension-free Vaginal	4 wl 5 de 6 7 8 9	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he means we're continuing the exhibit numbers that were marked from
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34 Exhibit 21 Gynecare TVT 43 Tension-free Vaginal Tape System - Instructions For Use  PREVIOUSLY MARKED EXHIBITS  NUMBER DESCRIPTION REFERENCED	4 wl 5 de 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 co	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he means we're continuing the exhibit numbers that were marked from Dr. Pramudji's prior deposition that was this morning and then yesterday in the Prolift, Prosima and Gynemesh PS cases.  MR. FAES: Right. And we may actually, we are going to refer back to some of those exhibits as well.  A. This is my expert report ontaining my opinions about the TVT.
5 6 7 8 9 10 11 12 13 14 15 16 17 18	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34 Exhibit 21 Gynecare TVT 43 Tension-free Vaginal Tape System - Instructions For Use  PREVIOUSLY MARKED EXHIBITS  NUMBER DESCRIPTION REFERENCED	4 wl 5 de 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 co 21 B	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he means we're continuing the exhibit numbers that were marked from Dr. Pramudji's prior deposition that was this morning and then yesterday in the Prolift, Prosima and Gynemesh PS cases.  MR. FAES: Right. And we may actually, we are going to refer back to some of those exhibits as well.  A. This is my expert report ontaining my opinions about the TVT.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34 Exhibit 21 Gynecare TVT 43 Tension-free Vaginal Tape System - Instructions For Use  PREVIOUSLY MARKED EXHIBITS  NUMBER DESCRIPTION REFERENCED	4 wl 5 de 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 co 21 B' 22	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he means we're continuing the exhibit numbers that were marked from Dr. Pramudji's prior deposition that was this morning and then yesterday in the Prolift, Prosima and Gynemesh PS cases.  MR. FAES: Right. And we may actually, we are going to refer back to some of those exhibits as well.  A. This is my expert report ontaining my opinions about the TVT.  Y MR. FAES:  Q. Does this report contain each
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Christina Pramudji, M.D.  Exhibit 19 CV of Christina Klein 14 Pramudji Exhibit 20 04/21/2014 E-mail String 34 Exhibit 21 Gynecare TVT 43 Tension-free Vaginal Tape System - Instructions For Use  PREVIOUSLY MARKED EXHIBITS  NUMBER DESCRIPTION REFERENCED	4 wl 5 de 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 co 21 B 22 23 of	hat's been marked as Exhibit No. 18 to your position. Can you tell me what that is?  MR. GAGE: And just for the record, when he says, "We're continuing the exhibit numbers," he means we're continuing the exhibit numbers that were marked from Dr. Pramudji's prior deposition that was this morning and then yesterday in the Prolift, Prosima and Gynemesh PS cases.  MR. FAES: Right. And we may actually, we are going to refer back to some of those exhibits as well.  A. This is my expert report ontaining my opinions about the TVT.

3 (Pages 6 to 9)

	Page 10		Page 12
1	A. Yes, thus far.	1	estimate that you spent?
2	Q. Now, this report discussed	2	A. Maybe ten hours.
3	various facts. Did you discuss the facts in	3	Q. And what previous report did
4	your report that you felt were the most	4	you modify to create the report that's in
5	important to you in drawing your opinions in	5	front of you?
6	this report?	6	A. I had done a TVT report in a
7	A. Yes.	7	previous case, I think it was was it
8	Q. And there are articles cited	8	Bellew, if I remember correctly.
9	here in your report. And in terms of your	9	Q. I don't think it was Bellew.
10	decision-making and writing the report, why	10	A. No. Oh, Huskey. Huskey.
11	did you cite to those articles in your	11	Q. Okay. And that report was
12	report?	12	issued in 2014; is that correct?
13	A. I felt like those articles had	13	A. That sounds about right.
14	the best level I data, as far as randomized	14	Q. So you hadn't updated your TVT
15	control trials, and reviews which were the	15	or TVT-O opinions between 2014 and when this
16	most rigorous.	16	report was signed in February of this year?
17	BY MR. FAES:	17	A. I believe that's correct.
18		18	
	Q. And you've also got a reliance	19	
19	list which is in front of you, which is	20	new opinions that you have that are contained
20	previously marked as Exhibit 13 in your		within this report that are important to you
21	previous deposition. Is that all is that	21	that have changed since the last time you
22	a list of all the material that you've	22	were deposed in 2014 and testified?
23	reviewed and relied upon for your TVT and	23	A. No.
24	TVT-O opinions in addition to the materials	24	Q. Doctor, I've added up the
	Page 11		Page 13
1	cited in your report?	1	number of hours that you estimate you've
2	A. Yes, I believe so.	2	worked for these Wave 1 cases. You told me
3	Q. Are there any materials that	3	that you estimated between 30 and 50 hours
4	you reviewed or relied upon in forming your	4	for each case-specific report, which would
5	opinions that are not either listed in your	5	put you between 420 and 700 hours. Do you
6	report marked as Exhibit 18 or in your	6	have any reason to disagree with my math on
7	reliance list marked as Exhibit 13?	7	that?
8	A. Not that I can think of right	8	A. No, that sounds right.
9	now.	9	Q. And those hours would be billed
10	Q. Can you tell me when you were	10	at \$600 an hour, correct?
11	first contacted about being an expert for	11	A. Correct.
12	this case, meaning this particular report? I	12	Q. So if you multiply those
13	know you've served as an expert for TVT and	13	numbers, I estimate that you will be paid
14	TVT-O in the past, but when were you first	14	approximately between 252,000 and \$420,000
15	contacted to be an expert for this particular	15	just for your case-specific opinions in this
16	wave?	16	Wave 1; is that correct?
17	A. I believe it was in November of	17	A. That sounds like correct math.
18	2015.	18	Q. And in addition, you'll bill
19	Q. And how many hours would you	19	approximately \$36,000 for your TVT-O general
20	say you've spent completing your general	20	report and your Prosima Gynemesh PS and
21	report?	21	Prolift report, based on 50 hours for the
	A. Well, I just had to modify a	22	Prosima, Prolift, Gynemesh PS report and
22			
22		23	
22 23 24	previous report, so it wasn't that much time.  Q. And how many hours would you	23 24	ten hours for the TVT report. Does that sound correct?

4 (Pages 10 to 13)

_	Page 14		Page 16
1	A. Yes.	1	of the sling or the mechanically cut version
2	Q. So in total, if my math is	2	of the sling?
3	correct, you stand to be paid by Ethicon's	3	A. I don't know.
4	attorneys somewhere between 288,000 and	4	Q. Do you know how to tell the
5	\$456,000 for the reports you've issued in	5	difference if you were to pick up the box?
6	this Wave 1?	6	A. I believe that the no, I
7	A. Yes.	7	really don't.
8	Q. Doctor, you've provided a CV	8	Q. And you do know that both the
9	with your report; is that correct?	9	TVT Exact and the TVT Abbrevo products are
10	A. Yes.	10	only offered in laser cut mesh, right?
11	Q. I'll make another copy of your	11	A. I don't really know. I don't
12	CV as 19. It's one that was with the report,	12	really pay attention.
13	but I don't think that's going to materially	13	Q. You don't know?
14	affect the questions I'm going to ask.	14	A. It doesn't matter clinically.
15	(Deposition Exhibit 19 marked.)	15	Q. Do you are you currently
16	BY MR. FAES:	16	still using the Solyx device?
17	Q. Doctor, within your CV is a	17	A. No.
18	list of publications. Do any of the	18	Q. Did you ever end up enrolling
19	publications in your CV specifically address	19	any patients for the Solyx clinical trial?
20	the TVT or TVT-O?	20	A. No. I moved practices in
21	A. No.	21	the midstream of setting up that trial,
22		22	and it was just too cumbersome to try to set
23	Q. You've never published in the	23	it up and start my own business at the same
24	area of sling complications; is that right?  A. That's correct.	24	time.
24		24	
	Page 15	,	Page 17
1	Q. Do any of your publications	1	Q. Have you implanted any Solyx
2	specifically address midurethral	2	devices in the last three years?
3	polypropylene slings?	3	A. No, I don't believe so.
4	A. No.	4	Q. Have you implanted any products
L L		_	
5	Q. I realize you've been asked	5	other than strike that.
6	this, but it's been a couple of years.	6	other than strike that.  Have you implanted any
6 7	this, but it's been a couple of years.  Doctor, what slings do you currently use?	6 7	other than strike that.  Have you implanted any midurethral polypropylene slings other than
6 7 8	this, but it's been a couple of years.  Doctor, what slings do you currently use?  A. Currently use the TVT Exact,	6 7 8	other than strike that.  Have you implanted any midurethral polypropylene slings other than the TVT Exact, TVT-O and TVT Abbrevo in the
6 7 8 9	this, but it's been a couple of years.  Doctor, what slings do you currently use?  A. Currently use the TVT Exact,  TVT Obturator and TVT Abbrevo.	6 7 8 9	other than strike that.  Have you implanted any midurethral polypropylene slings other than the TVT Exact, TVT-O and TVT Abbrevo in the last three years?
6 7 8 9 10	this, but it's been a couple of years.  Doctor, what slings do you currently use?  A. Currently use the TVT Exact,  TVT Obturator and TVT Abbrevo.  Q. Have you done preceptorships	6 7 8 9 10	other than strike that.  Have you implanted any midurethral polypropylene slings other than the TVT Exact, TVT-O and TVT Abbrevo in the last three years?  A. I think I tried the Mini-Arc
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	this, but it's been a couple of years.  Doctor, what slings do you currently use?  A. Currently use the TVT Exact,  TVT Obturator and TVT Abbrevo.  Q. Have you done preceptorships  for all three of those products?  A. I have not done preceptorships  for TVT Exact and retropubic TVT, but I did  do preceptorships for Obturator and Abbrevo.  Q. That's what I thought you were  going to say. So you no longer, at least  currently, use the TVT retropubic or classic  TVT product; you only use the TVT Exact,  which I understand is also a retropubic  sling, but it's not the original 1998  version, correct?  A. Correct.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	other than strike that.  Have you implanted any midurethral polypropylene slings other than the TVT Exact, TVT-O and TVT Abbrevo in the last three years?  A. I think I tried the Mini-Arc once or twice.  Q. So it's A. But that's all I can remember. Q. What would you say is your sling of choice right now? A. In my hands, I really like the TVT Exact. Q. What percentage of the time would you say you implant that device as compared to the other slings? A. Probably 95 percent of the time.
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5 (Pages 14 to 17)

	Page 18		Page 20
1	TVT-O or TVT Abbrevo procedure?	1	Scientific products.
2	A. I tend to use those more for	2	Q. Are you still a consultant for
3	patients with occult stress incontinence when	3	Boston Scientific?
4	I'm doing a prolapse repair, or if they have	4	A. No.
5	any sign of a weak bladder or poor emptying,	5	Q. When did that relationship end?
6	I might be more inclined to do those slings	6	A. I think it's been a couple of
7	rather than the retropubic.	7	years since I did anything with them. A year
8	Q. Okay. Has Ethicon ever asked	8	or two. I can't recall.
9	you to offer your opinions on the TVT-Secur	9	Q. Are there any other mesh
10	sling as an expert?	10	companies that you are currently doing
11	A. No.	11	consulting work for?
12	Q. What about the Abbrevo?	12	A. No.
13	A. No.	13	Q. Are there any other medical
14	Q. Or the Exact, TVT Exact?	14	device companies that you are currently doing
15	A. I don't think so.	15	consulting work for?
16	Q. What other surgical procedures	16	A. Not right now.
17	do you currently perform for the treatment of	17	Q. Are there any other
18	stress urinary incontinence other than the	18	pharmaceutical companies that you're
19	three products you mentioned?	19	currently doing any consulting work for?
20	A. I also do autologous fascial	20	A. No, not right now.
21	slings. I do biological midurethral I	21	Q. Would it be fair to say that
22	should say biological retropubic slings with	22	you've been pretty loyal to Ethicon's stress
23	a biological graft and Coaptite periurethral	23	urinary incontinence products in terms of
24	bulking.	24	polypropylene slings for the last
			- 11 1
	Page 19		Page 21
1	Q. Is that a surgical procedure?	1	three years?
2	A. Yes.	2	A. Yes.
3	Q. Would you say that your use of	3	Q. In your report on page 7, you
4	autologous fascial slings and biological	4	state that you've reviewed the expert reports
5	slings has increased in the last few years?	5	submitted by plaintiffs, specifically
6 7	A. No, it's stable.	6 7	Drs. Rosenzweig, Margolis and Carey. Is that
-	Q. What biological slings do you		correct?
8	currently use?	8	A. Yes.
9	A. I usually there's no, you	9	Q. Do you recall, have you
10	know, kit or marketed product for that, so I	10	reviewed any other expert reports in this
11	usually fashion it out of Xenform,	11 12	wave?
1 つ	Y and a r m matarial		A Degarding TVT9
12	X-e-n-f-o-r-m, material.	l .	A. Regarding TVT?
13	Q. That's a Boston Scientific	13	Q. Yes.
13 14	Q. That's a Boston Scientific product, right?	13 14	<ul><li>Q. Yes.</li><li>A. Not that I can recall right</li></ul>
13 14 15	<ul><li>Q. That's a Boston Scientific product, right?</li><li>A. Yes.</li></ul>	13 14 15	Q. Yes. A. Not that I can recall right now.
13 14 15 16	<ul><li>Q. That's a Boston Scientific product, right?</li><li>A. Yes.</li><li>Q. Do you know if you're currently</li></ul>	13 14 15 16	Q. Yes. A. Not that I can recall right now. Q. You also state that you
13 14 15 16 17	<ul> <li>Q. That's a Boston Scientific product, right?</li> <li>A. Yes.</li> <li>Q. Do you know if you're currently using any other Boston Scientific products</li> </ul>	13 14 15 16 17	<ul> <li>Q. Yes.</li> <li>A. Not that I can recall right now.</li> <li>Q. You also state that you reviewed the materials cited in the reports</li> </ul>
13 14 15 16 17 18	<ul> <li>Q. That's a Boston Scientific product, right?</li> <li>A. Yes.</li> <li>Q. Do you know if you're currently using any other Boston Scientific products other than Xenform, except for potentially</li> </ul>	13 14 15 16 17 18	Q. Yes. A. Not that I can recall right now. Q. You also state that you reviewed the materials cited in the reports and their expert depositions; is that
13 14 15 16 17 18 19	<ul> <li>Q. That's a Boston Scientific product, right?</li> <li>A. Yes.</li> <li>Q. Do you know if you're currently using any other Boston Scientific products other than Xenform, except for potentially you may be using the Uphold product in the</li> </ul>	13 14 15 16 17 18 19	Q. Yes. A. Not that I can recall right now. Q. You also state that you reviewed the materials cited in the reports and their expert depositions; is that correct?
13 14 15 16 17 18 19 20	Q. That's a Boston Scientific product, right? A. Yes. Q. Do you know if you're currently using any other Boston Scientific products other than Xenform, except for potentially you may be using the Uphold product in the future as you mentioned earlier?	13 14 15 16 17 18 19 20	Q. Yes. A. Not that I can recall right now. Q. You also state that you reviewed the materials cited in the reports and their expert depositions; is that correct? A. Yes.
13 14 15 16 17 18 19 20 21	Q. That's a Boston Scientific product, right?  A. Yes. Q. Do you know if you're currently using any other Boston Scientific products other than Xenform, except for potentially you may be using the Uphold product in the future as you mentioned earlier?  A. They have a vaginal manipulator	13 14 15 16 17 18 19 20 21	Q. Yes. A. Not that I can recall right now. Q. You also state that you reviewed the materials cited in the reports and their expert depositions; is that correct? A. Yes. Q. Did you review every single
13 14 15 16 17 18 19 20 21 22	Q. That's a Boston Scientific product, right? A. Yes. Q. Do you know if you're currently using any other Boston Scientific products other than Xenform, except for potentially you may be using the Uphold product in the future as you mentioned earlier? A. They have a vaginal manipulator that I use during sacrocolpopexy. That's the	13 14 15 16 17 18 19 20 21 22	Q. Yes. A. Not that I can recall right now. Q. You also state that you reviewed the materials cited in the reports and their expert depositions; is that correct? A. Yes. Q. Did you review every single document that they cited in their reports?
13 14 15 16 17 18 19 20 21	Q. That's a Boston Scientific product, right?  A. Yes. Q. Do you know if you're currently using any other Boston Scientific products other than Xenform, except for potentially you may be using the Uphold product in the future as you mentioned earlier?  A. They have a vaginal manipulator	13 14 15 16 17 18 19 20 21	Q. Yes. A. Not that I can recall right now. Q. You also state that you reviewed the materials cited in the reports and their expert depositions; is that correct? A. Yes. Q. Did you review every single

6 (Pages 18 to 21)

	Page 22		Page 24
1	you?	1	Ultrapro is because Ethicon has chosen not to
2	A. Butler Snow helped me to gather	2	market that device, correct?
3	them together.	3	A. I don't know the details behind
4	Q. Is there any particular	4	that.
5	reason actually yeah. Is there any	5	Q. Do you know what the TVT-O PA
6	particular reason why you chose to review the	6	is?
7	expert reports of just those three	7	A. No.
8	individuals?	8	Q. So I take it, then, that you
9	A. I can't remember if I reviewed	9	don't know whether or not the TVT-O PA was an
10	others, but I just have reviewed everything	10	obturator sling developed by Ethicon that had
11	that I could.	11	the Ultrapro mesh rather than the mesh that's
12	Q. If you've reviewed others, how	12	currently used in the TVT-O?
13	would I determine that? Are those listed on	13	A. No, I'm not familiar with that.
14	your reliance list or anywhere else?	14	Q. Do you know whether or not
15	A. Trying to remember.	15	Ethicon stated to the FDA that the TVT-O PA
16	MR. FAES: I mean, here's the	16	with the Ultrapro material was substantially
17	problem, William, is I don't even see	17	equivalent to the TVT-O?
18	these three listed on her reliance	18	MR. GAGE: Object to form.
19	list and there's only three listed in	19	A. I'm not familiar with that.
20	her report. So if there's other ones	20	BY MR. FAES:
21	she's reviewed, I need to know that.	21	Q. Is that something that would
22	MR. GAGE: All right.	22	change your opinion on whether or not there
23	BY MR. FAES:	23	is clinical data on the use of the Ultrapro
24	Q. Okay. Is the answer you don't	24	mesh as it relates to SUI patients if the
	i		
	Dage 23		Dage 25
1	Page 23	1	Page 25
1 2	recall at this time?	1	manufacturer of the ULTRAPRO mesh told the
2	recall at this time?  A. Yeah, I can't recall right now.	2	manufacturer of the ULTRAPRO mesh told the FDA that it was substantially equivalent to
2 3	recall at this time?  A. Yeah, I can't recall right now.  Q. We'll just move on. On page 18	2 3	manufacturer of the ULTRAPRO mesh told the FDA that it was substantially equivalent to the TVT-O already on the market?
2 3 4	recall at this time?  A. Yeah, I can't recall right now.  Q. We'll just move on. On page 18 of your report, you state that you "know of	2 3 4	manufacturer of the ULTRAPRO mesh told the FDA that it was substantially equivalent to the TVT-O already on the market?  MR. GAGE: Object to form.
2 3 4 5	recall at this time?  A. Yeah, I can't recall right now. Q. We'll just move on. On page 18 of your report, you state that you "know of no pelvic floor surgeons in the state of	2 3 4 5	manufacturer of the ULTRAPRO mesh told the FDA that it was substantially equivalent to the TVT-O already on the market?  MR. GAGE: Object to form.  A. I don't know.
2 3 4 5 6	recall at this time?  A. Yeah, I can't recall right now.  Q. We'll just move on. On page 18 of your report, you state that you "know of no pelvic floor surgeons in the state of Texas or in the United States who use PVDF or	2 3 4 5 6	manufacturer of the ULTRAPRO mesh told the FDA that it was substantially equivalent to the TVT-O already on the market?  MR. GAGE: Object to form.  A. I don't know. BY MR. FAES:
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7 (Pages 22 to 25)

Page 26 Page 28 1 Ethicon engineers worked on the problem of 1 be no clinically significant effect; is that 2 the Ultrapro mesh sticking to the sheaths 2 correct? during the sheath removal and ultimately 3 3 A. Absolutely. 4 solved that problem? 4 So it's your opinion that a O. 5 MR. GAGE: Object to form. 5 particle of Prolene that's directly under the 6 A. I can't recall right now. 6 skin of the vagina couldn't cause pain or 7 7 discomfort for the patient? BY MR. FAES: 8 Q. If that were indeed the case 8 A. That's correct. 9 9 and Ethicon engineers had solved that Even in the vagina, where problem, is that something that could 10 10 there's friction, if there were friction -potentially change your opinion, that the if there were a piece of Prolene directly 11 11 12 Ultrapro mesh would stick to the sheath and 12 underneath the skin in the vagina and you 13 tear apart upon sheath removal, losing 13 know in the vagina there's friction that 14 integrity? 14 occurs during intercourse, you don't believe A. Sure. 15 that that could cause discomfort or pain 15 You state on page 21 of your 16 under any circumstance? 16 O. 17 report that pain and dyspareunia can occur 17 MR. GAGE: Object to form. 18 with all surgeries, as can organ damage and 18 A. No. What I would clarify is 19 bladder perforation. And on the following 19 that, yes, any Prolene suture, mesh, page -- is that correct, first of all? 2.0 particles, if they're too superficial, then, 20 21 Yes, that's correct. 21 yeah, that could cause discomfort. We see A. 22 On the following page you say, 22 sutures that are used in prolapse repairs O. "Moreover these risks are obvious to pelvic that will be right under the surface and that 2.3 23 2.4 floor surgeons performing SUI surgeries," 24 can cause friction and irritation. Page 27 Page 29 giving their described surgical techniques 1 BY MR. FAES: 1 2 and instruments and materials used during SUI 2 Q. So you would agree that if a 3 particle from a TVT became loose and became 3 surgery. 4 4 too superficial in the vagina, it could cause Is that correct? 5 discomfort or pain, particularly during 5 A. Yes. 6 6 friction from intercourse? Q. Do you know whether pain and 7 7 dyspareunia, organ damage and bladder A. If it were too superficial and perforation are warned about in the IFU? 8 8 there was some irritation around it, it's 9 A. I would have to review it to 9 potential. But the particle issue is really 10 say definitively. 10 not an issue. It's really not something that Q. Well, I'll represent to you 11 we see clinically. I have never gone in to a 11 12 that, at least as of 2015, all of those risks 12 patient -- you know, do surgery on a patient 13 are now in the IFU. So assuming that to be 13 and found a particle to be a source of pain 14 true, if they are obvious, do you have an 14 or causing problems at all. 15 opinion as to why Ethicon chose to include 15 MR. FAES: I'm going to object them in their IFU anyway as of 2015? and move to strike after the word 16 16 17 MR. GAGE: Object to form. 17 "potential." A. I'm not sure why they put them 18 18 BY MR. FAES: in. I don't have a problem with it. I don't 19 19 Q. You go on to say on the same 20 think it's necessary, but it's reasonable. 20 page that, "Also, during the surgery, the 2.1 BY MR. FAES: 21 site can be irrigated and suctioned, which You state on page 28 of your 22 would dispose of any particles." 2.2 report that even if particles from the TVT 23 23 Is that correct? mesh were to get into the vagina, there would 24 24 That's correct.

8 (Pages 26 to 29)

1 Q. Isn't it true that the site 2 can't be irrigated and suctioned if the 3 particle becomes loose after the surgery is 4 completed and the incision is closed? 5 A. That doesn't happen. 6 Q. That was not my question, 7 whether or not it happens. My question was, 7 you don't believe that that causes a clinical concerns to the patient if to metal particle gets into the body b it's in the packaging? 5 MR. GAGE: Object to form the package that when particles in the package that when	-
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	you take
8 isn't it true that the site can't be 8 out the instruments and the implan	
9 irrigated and suctioned if a particle becomes 9 are not going to go into the patien	
10 loose after the surgery is completed and the 10 then you added in the part about it	
11 incision is closed? 11 embedded in the mesh. So can yo	_
12 A. Yes, that is correct, to answer 12 what you mean by that?	Ĭ
13 that hypothetical question. 13 BY MR. FAES:	
14 Q. You state on page 29 of your 14 Q. Well, let me ask you this	. If
report that, "The protective sheath over the 15 there's a if there's metal particle	
mesh bears the forces as the mesh is passed 16 in the TVT mesh packaging, that of	
through the pelvis and as noted the mesh is 17 potentially get imbedded in the mesh	
18 placed tension free and spaced from the 18 correct?	
19 urethra with an instrument like a dilator 19 MR. GAGE: Object to for	rm.
20 before removing the sheaths." 20 A. I can't envision that	
21 Is that correct? 21 happening.	
22 A. That's correct. 22 BY MR. FAES:	
Q. So as you've stated here, 23 Q. Let me ask you this. If a	
you've seen a surgeon before use a Babcock or 24 if, hypothetically, a metal particle	
Page 31	Page 33
1 other instrument to hold the tape in place 1 embedded in the mesh and the surge	eon didn't
while the sheaths are removed, correct?  2 notice it and it got implanted into the	
3 A. Correct. 3 patient with metal particles in the m	
4 Q. Would you have you ever seen 4 could that cause a clinical concern?	,
5 a procedural video that was sent out to 5 MR. GAGE: Object to form	n.
6 physicians where the mesh appears to be being 6 A. I really don't know, because	
7 stretched at that localized point where it's 7 do metal implants in orthopedic sur	
8 being held in place by the Babcock while the 8 I I don't know the answer to that	
9 sheaths are being removed? 9 question.	
10 A. I can't recall as I sit here 10 BY MR. FAES:	
11 right now. 11 Q. Would you knowingly imp	olant a
12 Q. You also state, "Metal 12 TVT product that it appeared that the	
13 particle" strike that. 13 foreign matter or metal within the n	
14 You also state that, "Mesh 14 MR. GAGE: Object to form	
15 particles seen in packaging are also of no 15 BY MR. FAES:	
16 clinical concern." 16 Q. Or would you go go to t	he
17 Is that correct? 17 shelf and get out a different one tha	
18 A. That's correct. 18 have that problem?	
19 Q. Is your opinion the same if 19 MR. GAGE: Object to form	n.
20 there are metal particles seen in packaging, 20 A. If I saw some metal in the	re, I
21 that those pose no clinical concern? 21 would probably go get another devi	ce or clean
22 A. That's correct. 22 it off or something.	
Q. So if there's metal particles 23 BY MR. FAES:	
24 in the packaging or embedded within the mesh, 24 Q. Do you know where the T	VT and

9 (Pages 30 to 33)

_	Page 34		Page 36
1	TVT-O are manufactured?	1	the surgery and your relationship with
2	A. No, I don't.	2	Ethicon. Are you available to talk to me
3	Q. Well, I'll represent to you	3	this week? I've also been trying to reach
4	they're manufactured in Neuchâtel,	4	your colleague Dr. Melvyn Anhalt, though I
5	Switzerland, which I'm sure the court	5	haven't heard back yet."
6	reporter does not know how to spell.	6	Do you see that?
7	Were you aware that in 2010,	7	A. Yes.
8	the entire TVT-O and TVT production lines	8	Q. And this e-mail gets forwarded
9	were shut down because there was an excess of	9	to Burt Snell at Butler Snow; is that
10	foreign materials in the product in	10	correct?
11	packaging?	11	A. Yes.
12	MR. GAGE: Object to form.	12	Q. It's forwarded by you. And
13	A. No, I was not aware of that.	13	Burt Snell is a lawyer for Ethicon, who was
14	BY MR. FAES:	14	actually here yesterday helping you prepare
15	Q. Do you think that could	15	for your deposition; is that correct?
16	potentially cause a clinical impact if there	16	A. That's correct.
17	were foreign matter in the products in	17	Q. First of all, do you recall if
18	packaging of the TVT and TVT-O? Do you have	18	you ever replied to Amy Silverstein regarding
19	any opinion on that?	19	this message?
20	A. I don't really have an opinion	20	A. No, I did not.
21	on it.	21	Q. Have you ever spoken to the
22	(Deposition Exhibit 20 marked.)	22	press about mesh used for pelvic organ
23	BY MR. FAES:	23	prolapse or stress urinary incontinence?
24	Q. Doctor, I'm going to hand you	24	A. Not that I can recall.
1	Page 35		Page 37
		1 1	O Do you recall any norticular
1	what's been marked as Exhibit 20 to your	1	Q. Do you recall any particular
2	deposition, as soon as I get it out and get	2	reason why you chose not to respond to this
2	deposition, as soon as I get it out and get it marked.	2 3	reason why you chose not to respond to this e-mail?
2 3 4	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not	2 3 4	reason why you chose not to respond to this e-mail?  A. No, I don't remember.
2 3 4 5	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not the updated CV? Does that matter?	2 3 4 5	reason why you chose not to respond to this e-mail?  A. No, I don't remember.  Q. Do you know if Dr. Anhalt ever
2 3 4 5 6	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not the updated CV? Does that matter?  Q. Does it affect the answers to	2 3 4 5 6	reason why you chose not to respond to this e-mail?  A. No, I don't remember.  Q. Do you know if Dr. Anhalt ever spoke with Ms. Silverstein or anyone else in
2 3 4 5 6 7	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not the updated CV? Does that matter?  Q. Does it affect the answers to the questions I asked you?	2 3 4 5 6 7	reason why you chose not to respond to this e-mail?  A. No, I don't remember.  Q. Do you know if Dr. Anhalt ever spoke with Ms. Silverstein or anyone else in the press?
2 3 4 5 6 7 8	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not the updated CV? Does that matter?  Q. Does it affect the answers to the questions I asked you?  A. No.	2 3 4 5 6 7 8	reason why you chose not to respond to this e-mail?  A. No, I don't remember. Q. Do you know if Dr. Anhalt ever spoke with Ms. Silverstein or anyone else in the press?  A. I don't know.
2 3 4 5 6 7 8	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not the updated CV? Does that matter?  Q. Does it affect the answers to the questions I asked you?  A. No.  Q. No, then it doesn't.	2 3 4 5 6 7 8 9	reason why you chose not to respond to this e-mail?  A. No, I don't remember. Q. Do you know if Dr. Anhalt ever spoke with Ms. Silverstein or anyone else in the press?  A. I don't know. Q. Now, this is dated April 21st,
2 3 4 5 6 7 8 9	deposition, as soon as I get it out and get it marked.  A. Is it material that this is not the updated CV? Does that matter?  Q. Does it affect the answers to the questions I asked you?  A. No.  Q. No, then it doesn't.  A. Okay.	2 3 4 5 6 7 8 9	reason why you chose not to respond to this e-mail?  A. No, I don't remember. Q. Do you know if Dr. Anhalt ever spoke with Ms. Silverstein or anyone else in the press? A. I don't know. Q. Now, this is dated April 21st, 2014. Do you recall that this was about a
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10 (Pages 34 to 37)

	Page 38		Page 40
1	talk about.	1	BY MR. FAES:
2	Q. Have you ever spoken to the	2	Q. Recurrence of incontinence?
3	press about your relationship with Ethicon,	3	A. Yes, as in other incontinence
4	as this reporter was requesting?	4	surgeries.
5	A. I don't believe so.	5	MR. FAES: Object and move to
6	Q. Is that because you would	6	strike after the answer.
7	prefer to keep the details about your	7	BY MR. FAES:
8	relationship with Ethicon and Johnson &	8	Q. Bleeding, including hemorrhage
9	Johnson private?	9	or hematoma?
10	A. I don't have any reason to keep	10	A. Yes, as in other surgeries.
11	it private.	11	MR. FAES: Object and move to
12	Q. Doctor, I'm going to ask you	12	strike after the answer.
13	about some adverse reactions and I'm going to	13	BY MR. FAES:
14	ask if ask you whether or not you believe	14	Q. One or more revision surgeries
15	these are adverse events that can be	15	may be necessary to treat these adverse
16	associated with the TVT or TVT-O product.	16	reactions?
17	Okay?	17	A. Yes, as in other pelvic
18	A. Okay.	18	surgeries.
19	Q. Acute and/or chronic pain?	19	MR. FAES: Object and move to
20	A. Yes, as in other pelvic	20	strike after the answer.
21	surgeries.	21	BY MR. FAES:
22	MR. FAES: Object and move to	22	Q. Prolene mesh is a permanent
23	strike after the answer "yes."	23	implant that integrates into the tissue. In
24	strike after the answer yes.	24	cases where the Prolene mesh needs to be
		24	
	Page 39		Page 41
	DILLED ELEG	_	1. 1. 1. 1. 1.
1	BY MR. FAES:	1	removed in part or whole, significant
2	Q. Voiding dysfunction?	2	dissection may be required?
2 3	<ul><li>Q. Voiding dysfunction?</li><li>A. Yes, as in other pelvic</li></ul>	2	dissection may be required?  A. Yes, as could occur with
2 3 4	<ul><li>Q. Voiding dysfunction?</li><li>A. Yes, as in other pelvic surgeries.</li></ul>	2 3 4	dissection may be required?  A. Yes, as could occur with sutures in other pelvic surgeries.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	<ul> <li>Q. Voiding dysfunction?</li> <li>A. Yes, as in other pelvic surgeries.</li> <li>MR. FAES: Object and move to strike after the answer.</li> <li>BY MR. FAES:</li> <li>Q. Pain with intercourse which in some patients may not resolve?</li> <li>A. Yes, as in other pelvic surgeries.</li> <li>Q. I just have  MR. FAES: Object and move to strike after the answer.</li> <li>BY MR. FAES:</li> <li>Q. Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur?</li> <li>A. Yes, as in other pelvic surgeries.</li> </ul>	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	dissection may be required?  A. Yes, as could occur with sutures in other pelvic surgeries.  MR. FAES: Object and move to strike after the answer.  BY MR. FAES: Q. Seroma? A. Yes, as in other pelvic surgeries.  MR. FAES: Object and move to strike after the answer.  BY MR. FAES: Q. Urge incontinence? A. Yes, as in other pelvic surgeries.  MR. FAES: Object and move to strike after the answer.  BY MR. FAES: Object and move to strike after the answer.  BY MR. FAES: Object and move to strike after the answer.  BY MR. FAES: Q. Urinary frequency? A. Yes, as in other pelvic
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11 (Pages 38 to 41)

	Page 42		Page 44
1	BY MR. FAES:	1	BY MR. FAES:
2	Q. Urinary retention?	2	Q. Yeah, I'll re-ask the question
3	A. Yes, as in other pelvic	3	for the record to correct it. Doctor, are
4	surgeries.	4	you aware of whether or not these are all
5	MR. FAES: Object and move to	5	adverse reactions that were added to the TVT
6	strike after the answer.	6	and TVT-O IFU in May of 2015?
7	BY MR. FAES:	7	A. Yes.
8	Q. Adhesion formation?	8	Q. See, don't just agree with
9	A. Yes, as in other pelvic	9	whatever I say.
10	surgeries.	10	MR. GAGE: See, I was getting
11	MR. FAES: Object and move to	11	ready to I was going to do a
12	strike after the answer.	12	speaking objection on that, if she had
13	BY MR. FAES:	13	not clarified it.
14	Q. Atypical vaginal discharge?	14	BY MR. FAES:
15	A. Yes, as in other pelvic	15	Q. Doctor, do you know whether or
16	surgeries.	16	not the list of adverse reactions that were
17	MR. FAES: Object and move to	17	added in May of 2015 are all risks that
18	strike after the answer.	18	Ethicon knew about at the time the TVT was
19	BY MR. FAES:	19	first launched in 2008?
20	Q. Exposed mesh may cause pain or	20	A. The TVT was first launched in
21	discomfort to the patient's partner during	21	2008?
22	intercourse?	22	Q. 1998. Thank you.
23	A. Yes, as can occur with exposed	23	A. I'm not sure.
24	sutures in other pelvic surgeries.	24	Q. You just you don't know one
21		21	
	Page 43	_	Page 45
1	MR. FAES: Object and move to	1	way or the other?
2	strike after the answer.	2	A. No.
3	BY MR. FAES:	3	Q. Are you aware that strike
4	Q. Death?	4	that.
5	A. Yes, as in any surgery.	5	Do you know why Ethicon chose
6	MR. FAES: Object and move to	6	to add these adverse events to its IFU in
7	strike after the answer.	7	2015?
8	BY MR. FAES:	8	A. My understanding is that the
9	Q. Doctor, are you aware of	9	Canadian board asked them to add some
10	whether or not these are all adverse	10	specific reactions, and they decided just to
11	reactions that were added to the TVT and	11	go ahead and put a long laundry list in
12	TVT-O IFU in May of 2014?	12	there.
13	MR. GAGE: Object to form.	13	Q. Do you believe that do you
14	A. I believe that's correct.	14	believe that these adding these strike
15	(Deposition Exhibit 21 marked.)	15	that.
16	BY MR. FAES:	16	Do you believe that Ethicon
17	Q. I'll go ahead and mark a copy	17	would've added all of these adverse reactions
18	of that just so you're not flying blind,	18	if they didn't believe they were necessary to
19	which is Exhibit 21.	19	support the continued sale of the device?
20	MR. FAES: You need one,	20	MR. GAGE: Object to form.
21	William?	21	A. Could you repeat that for me?
22	THE WITNESS: Is it 2015? Is	22	BY MR. FAES:
23 24	that what you meant to say?	23 24	Q. Sure. Do you believe that Ethicon would've added all these adverse

12 (Pages 42 to 45)

	Page 46		Page 48
1	reactions if they didn't believe they were	1	Q. Assuming that sales
2	necessary to support the continued sale of	2	representatives for Ethicon are not permitted
3	the device?	3	to discuss with doctors things that are not
4	MR. GAGE: Object to form.	4	contained within the IFU, would you agree
5	A. I don't know.	5	that this update would be helpful by allowing
6	BY MR. FAES:	6	sales representatives to discuss more
7	Q. Are you aware that Dr. Martin	7	potential risks of the product with their
8	Weisberg was designated by Ethicon as a	8	doctors?
9	corporate representative for why these IFU	9	A. Assuming that's true, then,
10	changes were made?	10	yes.
11	A. Yes, I'm familiar with that.	11	MR. FAES: I want to take just
12	Q. Have you read that deposition?	12	a quick five-minute break, and it will
13	A. No, I haven't.	13	help me get organized and focused on
14	Q. Do you think that's a	14	what I really need to do.
15	deposition that would be important to you in	15	(Recess Taken From 11:54 a.m.
16	forming your opinions on this case?	16	To 12:00 p.m.)
17	A. No.	17	BY MR. FAES:
18		18	Q. Doctor, we're back on the
19	Q. You don't think it's important to know why Ethicon chose to add these	19	record after a short break. Are you ready to
20	adverse reactions to their IFU?	20	proceed?
21		21	A. Yes.
22	A. It doesn't change my opinions.	22	
	Q. Would you agree that this is a	23	Q. Doctor, you said that you
23	significant IFU update?	24	believe you spent ten hours preparing your
24	A. They certainly added several	24	TVT and TVT-O report in this case?
	D 4.0		
	Page 47		Page 49
1	things on there, which I think is reasonable,	1	A. Correct.
2	things on there, which I think is reasonable, but I don't think it's necessary. I think it	2	<ul><li>A. Correct.</li><li>Q. Does that include all of the</li></ul>
	things on there, which I think is reasonable,		<ul><li>A. Correct.</li><li>Q. Does that include all of the time that you spent reviewing the expert</li></ul>
2 3 4	things on there, which I think is reasonable, but I don't think it's necessary. I think it	2	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by
2	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.	2	<ul><li>A. Correct.</li><li>Q. Does that include all of the time that you spent reviewing the expert</li></ul>
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2 3 4 5	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon	2 3 4 5	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey?
2 3 4 5 6	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon added to the IFU is helpful to pelvic	2 3 4 5 6	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey? A. Yes, since this was just an
2 3 4 5 6 7	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon added to the IFU is helpful to pelvic surgeons who may consider using the TVT?	2 3 4 5 6 7	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey? A. Yes, since this was just an update.
2 3 4 5 6 7 8	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon added to the IFU is helpful to pelvic surgeons who may consider using the TVT?  A. Not particularly, since pelvic	2 3 4 5 6 7 8	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey? A. Yes, since this was just an update. Q. So you believe it took you less
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon added to the IFU is helpful to pelvic surgeons who may consider using the TVT?  A. Not particularly, since pelvic surgeons are already familiar with all of these adverse reactions.  Q. You don't believe that adding this list of information to the IFU might help physicians better consent their patients for surgery with the TVT or TVT-O?  A. No.  Q. Would you agree that informed consent is frequently guided by the contents of an IFU for that particular device?  A. No, I don't think so.  Q. Do you know whether or not	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey? A. Yes, since this was just an update. Q. So you believe it took you less than ten hours to pull and look at every footnote and document that they cited plus update your report? A. I believe so. I can't remember specifically. Q. Doctor, have you reviewed the 2015 deposition of Laura Angelini, because I didn't see it on your reliance list? A. I can't recall if I did or not. Q. As someone who will be offering opinions on whether the TVT mesh frays, ropes, curls, unravels, loses particles or
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon added to the IFU is helpful to pelvic surgeons who may consider using the TVT?  A. Not particularly, since pelvic surgeons are already familiar with all of these adverse reactions.  Q. You don't believe that adding this list of information to the IFU might help physicians better consent their patients for surgery with the TVT or TVT-O?  A. No.  Q. Would you agree that informed consent is frequently guided by the contents of an IFU for that particular device?  A. No, I don't think so.  Q. Do you know whether or not Ethicon sales reps representatives are allowed to discuss with their doctors things	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey? A. Yes, since this was just an update. Q. So you believe it took you less than ten hours to pull and look at every footnote and document that they cited plus update your report? A. I believe so. I can't remember specifically. Q. Doctor, have you reviewed the 2015 deposition of Laura Angelini, because I didn't see it on your reliance list? A. I can't recall if I did or not. Q. As someone who will be offering opinions on whether the TVT mesh frays, ropes, curls, unravels, loses particles or deforms, wouldn't you want to have access to a deposition of a TVT product director
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	things on there, which I think is reasonable, but I don't think it's necessary. I think it was adequate before they added all those in.  Q. Do you believe that these additional adverse reactions that Ethicon added to the IFU is helpful to pelvic surgeons who may consider using the TVT?  A. Not particularly, since pelvic surgeons are already familiar with all of these adverse reactions.  Q. You don't believe that adding this list of information to the IFU might help physicians better consent their patients for surgery with the TVT or TVT-O?  A. No.  Q. Would you agree that informed consent is frequently guided by the contents of an IFU for that particular device?  A. No, I don't think so.  Q. Do you know whether or not Ethicon sales reps representatives are	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. Q. Does that include all of the time that you spent reviewing the expert reports and materials cited by Dr. Rosenzweig, Margolis and Carey? A. Yes, since this was just an update. Q. So you believe it took you less than ten hours to pull and look at every footnote and document that they cited plus update your report? A. I believe so. I can't remember specifically. Q. Doctor, have you reviewed the 2015 deposition of Laura Angelini, because I didn't see it on your reliance list? A. I can't recall if I did or not. Q. As someone who will be offering opinions on whether the TVT mesh frays, ropes, curls, unravels, loses particles or deforms, wouldn't you want to have access to

13 (Pages 46 to 49)

	Page 50		Page 52
1	deforming?	1	be some things that I miss here and there
2	MR. GAGE: Object to form.	2	unintentionally.
3	A. I don't think it would change	3	Q. Do you know whether or not Tom
4	my opinions, so no.	4	Divilio was the product director when the TVT
5	BY MR. FAES:	5	was launched?
6	Q. So you have no interest in	6	A. I don't know.
7	seeing that?	7	Q. As someone who will be offering
8	A. It would be interesting to see	8	opinions on whether or not the TVT mesh
9	it.	9	frays, ropes, curls, unravels, loses
10	Q. But you'd agree that prior to	10	particles and/or deforms, wouldn't you want
11	issuing your report in this case, you did not	11	to have access to a deposition where those
12	review that deposition?	12	things are being discussed by Ethicon's first
13	A. I can't recall.	13	medical director?
14	Q. If you had reviewed that	14	A. No, not necessarily. I don't
15	deposition, it would be on your reliance	15	think it would change my opinions.
16	list, correct?	16	Q. You don't think that the
17	A. Yes. But I may miss something	17	medical director at Ethicon who was there
18	here and there.	18	when the TVT was first launched in the United
19	Q. Do you know whether or not	19	States can offer you any insight as to
20	this the 2015 Laura Angelini deposition	20	whether or not the TVT is defective?
21	covered documents from the late 1990s and	21	MR. GAGE: Object to form.
22	early 2000s that showed Ethicon was on notice	22	A. I don't think that's going to
23	that the mesh used in the TVT frayed, roped,	23	trump my experience coupled with the
24	curled, unraveled and lost particles?	24	literature.
	, 1		
	Page 51		Page 53
1	Page 51  MR GAGE: Object to form	1	Page 53
1 2	MR. GAGE: Object to form.	1 2	BY MR. FAES:
2	MR. GAGE: Object to form.  A. I don't recall.	2	BY MR. FAES: Q. Didn't ask whether it would
2	MR. GAGE: Object to form. A. I don't recall. BY MR. FAES:	2 3	BY MR. FAES:  Q. Didn't ask whether it would trump your experience coupled with the
2 3 4	MR. GAGE: Object to form. A. I don't recall. BY MR. FAES: Q. Do you know whether or not	2 3 4	BY MR. FAES:  Q. Didn't ask whether it would trump your experience coupled with the literature. My question was, you don't think
2 3 4 5	MR. GAGE: Object to form. A. I don't recall. BY MR. FAES: Q. Do you know whether or not during that time frame, from 1998 to 2000,	2 3 4 5	BY MR. FAES:  Q. Didn't ask whether it would trump your experience coupled with the literature. My question was, you don't think that the medical director at Ethicon who was
2 3 4 5 6	MR. GAGE: Object to form.  A. I don't recall.  BY MR. FAES:  Q. Do you know whether or not during that time frame, from 1998 to 2000,  Ethicon initiated a mesh improvement product	2 3 4 5 6	BY MR. FAES:  Q. Didn't ask whether it would trump your experience coupled with the literature. My question was, you don't think that the medical director at Ethicon who was there when the TVT was first launched in the
2 3 4 5 6 7	MR. GAGE: Object to form. A. I don't recall. BY MR. FAES: Q. Do you know whether or not during that time frame, from 1998 to 2000, Ethicon initiated a mesh improvement product for the Prolene mesh but excluded the TVT	2 3 4 5 6	BY MR. FAES:  Q. Didn't ask whether it would trump your experience coupled with the literature. My question was, you don't think that the medical director at Ethicon who was there when the TVT was first launched in the United States can offer you any insight as to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. GAGE: Object to form.  A. I don't recall. BY MR. FAES: Q. Do you know whether or not during that time frame, from 1998 to 2000, Ethicon initiated a mesh improvement product for the Prolene mesh but excluded the TVT mesh from that product from that project? Sorry.  MR. GAGE: Object to form.  A. I don't know about that. BY MR. FAES: Q. Have you reviewed the October 2014 deposition of Tom Divilio? A. Sounds vaguely familiar. Q. Do you know whether or not that deposition is on your reliance list? A. I don't remember. I would have to look. Q. If it's not on your reliance list, does that mean you haven't reviewed the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. FAES:  Q. Didn't ask whether it would trump your experience coupled with the literature. My question was, you don't think that the medical director at Ethicon who was there when the TVT was first launched in the United States can offer you any insight as to whether or not the TVT is defective?  MR. GAGE: Object to form.  A. That's correct.  BY MR. FAES:  Q. The testimony is of Ethicon's first medical director when TVT was launched isn't information that you would want to consider in informing your in forming your opinions in this case?  A. I would consider it. I probably have looked at it, but it's not as important to me as the literature and my own experience, so no.  Q. Are you going to offer an

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1	Page 54		Page 56
	laser cut mesh?	1	A. Maybe technically they call it
2	A. Yes, that's correct.	2	a mini-sling. It has more length than the
3	Q. So if someone told you, for	3	Abbrevo, so that's where I distinguish it.
4	example, that a laser cut mesh needs to be	4	So I don't call it a mini-sling.
5	tensioned more loosely under the urethra, you	5	Q. What has more length than the
6	would disagree with that?	6	Abbrevo?
7	A. Yes.	7	A. I'm sorry, the Abbrevo has more
8	Q. Do you know whether or not	8	length than the Secur.
9	Ethicon's preceptors were telling doctors	9	Q. Right. But you know that the
10	that with regard to the laser cut mesh	10	Abbrevo is substantially shorter than the
11	products?	11	TVT-O product?
12	A. I don't recall that.	12	A. Correct.
13	Q. But you were you were a	13	Q. So I take it you would disagree
14	preceptor in fact, you still are a	14	with a physician if that physician said that
15	preceptor for Ethicon, right?	15	he had to lay his laser cut mesh slings in
16	A. No, I haven't done any	16	much tighter than the mechanically cut ones
17	preceptoring for a few years.	17	in order to achieve success with the device?
18	Q. Since 2013, right?	18	MR. GAGE: Object to form.
19	A. Correct.	19	A. Yes, I disagree.
20	Q. But you were a preceptor for	20	BY MR. FAES:
21	Ethicon from 2004 to 2013, right?	21	Q. Would you agree that a
22	A. Correct.	22	responsible medical device company would
23	Q. And when you were preceptoring	23	determine the proper way to place a device
24	for Ethicon, you never told anyone that the	24	before putting that product on the market?
	Page 55		Page 57
1	laser cut mesh needs to be tensioned any	1	A. In surgery, there can be more
2	differently than the mechanically cut mesh?	2	than one proper way to do things. So I think
3	A. Not that I can recall.	3	it's responsible for the company to do their
4	Q. Did you	4	best to figure out a good way to do it, but
5	A. It's pretty much the same.	5	there may be another way that evolves that's
6	Q. Did you ever tell anyone that	6	better.
7	the for example, the Abbrevo device needs	7	Q. So I'm not sure if I was clear
8	to be tensioned differently than the TVT or	8	on your answer. Do you agree or disagree
	TVT Exact?	9	that a responsible medical device company
9			1 11 1 4 4 1
10	A. No.	10	should determine the proper way to place a
10 11	Q. Do you know whether or not, in	11	device before putting that product on the
10 11 12	Q. Do you know whether or not, in fact, there are differences in the tensioning	11 12	device before putting that product on the market?
10 11 12 13	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact	11 12 13	device before putting that product on the market?  A. My answer would be yes, but
10 11 12 13 14	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?	11 12 13 14	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving
10 11 12 13 14 15	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?  A. I can't recall, but	11 12 13 14 15	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving and things may change over time. So what may
10 11 12 13 14 15	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?  A. I can't recall, but practically, it's the same. The only one	11 12 13 14 15 16	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving and things may change over time. So what may be proper at one time may not be proper later
10 11 12 13 14 15 16 17	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?  A. I can't recall, but practically, it's the same. The only one that was different was the mini-sling. But	11 12 13 14 15 16	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving and things may change over time. So what may be proper at one time may not be proper later on, or there may be something more optimal,
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10 11 12 13 14 15 16 17 18 19 20 21	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?  A. I can't recall, but practically, it's the same. The only one that was different was the mini-sling. But among the other ones, it's really pretty much the same tensioning.  Q. And by "mini-sling," what do you mean? You mean the TVT-Secur?	11 12 13 14 15 16 17 18 19 20 21	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving and things may change over time. So what may be proper at one time may not be proper later on, or there may be something more optimal, in other words.  MR. FAES: Object and move to strike after the answer "yes."  BY MR. FAES:
10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?  A. I can't recall, but practically, it's the same. The only one that was different was the mini-sling. But among the other ones, it's really pretty much the same tensioning.  Q. And by "mini-sling," what do you mean? You mean the TVT-Secur?  A. Correct.	11 12 13 14 15 16 17 18 19 20 21 22	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving and things may change over time. So what may be proper at one time may not be proper later on, or there may be something more optimal, in other words.  MR. FAES: Object and move to strike after the answer "yes."  BY MR. FAES:  Q. You were a preceptor for the
10 11 12 13 14 15 16 17 18 19 20 21	Q. Do you know whether or not, in fact, there are differences in the tensioning instructions between the TVT-O, the TVT Exact and the TVT Abbrevo?  A. I can't recall, but practically, it's the same. The only one that was different was the mini-sling. But among the other ones, it's really pretty much the same tensioning.  Q. And by "mini-sling," what do you mean? You mean the TVT-Secur?	11 12 13 14 15 16 17 18 19 20 21	device before putting that product on the market?  A. My answer would be yes, but recognizing that surgery is always evolving and things may change over time. So what may be proper at one time may not be proper later on, or there may be something more optimal, in other words.  MR. FAES: Object and move to strike after the answer "yes."  BY MR. FAES:

15 (Pages 54 to 57)

	Page 58		Page 60
1	Q. And you instructed other	1	A. Yes.
2	physicians on how to place that mesh?	2	Q. Would you agree that the
3	A. Yes.	3	properties of the mesh affect the safety
4	Q. Did anyone at Ethicon ever tell	4	profile of the mesh?
5	you that the Abbrevo device should be placed	5	A. Yes.
6	snugly so that the tissue pillows through the	6	Q. Would you agree that the pore
7	mesh?	7	size of the mesh is one property that affects
8	A. I don't recall that for	8	the safety profile of the mesh?
9	Abbrevo.	9	A. Yes.
10	Q. Do you know if that whether	10	Q. Would you agree that the
11	or not that was Ethicon's medical director's	11	density of the mesh is one property that
12	opinion of how the tensioning technique for	12	affects the safety profile of the mesh?
13	the Abbrevo should be described?	13	A. Yes. I think the pore size and
14	A. I don't recall that.	14	density are important, and I think they got
15	Q. As someone who taught the	15	it right.
16	Abbrevo device to other surgeons, is that	16	
17	· ·	17	Q. Do you agree that the weight of
18	information you would've wanted to know?		the mesh is a property that affects the
	A. No, because I knew how to do	18	safety profile of the mesh?  A. Yes.
19	it, I knew how to get the results, so I	19	
20	taught it the same way I taught the other	20	Q. Do you agree that the
21	ones.	21	elasticity of the mesh is a property that
22	Q. Do you know that Ethicon	22	affects the safety of the mesh?
23	actually solicited feedback from surgeons	23	A. Well, in the sense the
24	about the proper way to tension the TVT	24	elasticity can affect urinary retention if
	Page 59		Page 61
1	Page 59 Abbrevo device after it was launched?	1	it's too tight, so yes.
1 2		1 2	
	Abbrevo device after it was launched?		it's too tight, so yes.
2	Abbrevo device after it was launched?  A. I don't know about that.	2	it's too tight, so yes.  Q. Would you agree that stiffness
2 3	Abbrevo device after it was launched?  A. I don't know about that.  Q. Did they ever ask for your	2 3	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that
2 3 4	Abbrevo device after it was launched? A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the	2 3 4	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?
2 3 4 5	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall.	2 3 4 5	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible,
2 3 4 5 6	Abbrevo device after it was launched?  A. I don't know about that.  Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall.	2 3 4 5 6	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.
2 3 4 5 6 7	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your	2 3 4 5 6 7	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with
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2 3 4 5 6 7 8 9	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?	2 3 4 5 6 7 8 9	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."
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2 3 4 5 6 7 8 9 10 11 12	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?  A. I don't recall. Q. Would you have liked to have been asked for your feedback on how to properly tension the device since you seem	2 3 4 5 6 7 8 9 10 11	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."  BY MR. FAES:  Q. Would you agree that the surface area of the mesh is one property that affects the safety profile of the mesh?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?  A. I don't recall. Q. Would you have liked to have been asked for your feedback on how to properly tension the device since you seem pretty sure about how to correctly do it?  MR. GAGE: Object to form.  A. Sure.  BY MR. FAES: Q. Doctor, will you be offering opinions in this case related to the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."  BY MR. FAES:  Q. Would you agree that the surface area of the mesh is one property that affects the safety profile of the mesh?  A. I don't know that that has much bearing on the safety profile, so no.  Q. Do you agree that the tensile strength of the TVT mesh is one property that affects the safety profile of the mesh?  A. No, I think that speaks more to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?  A. I don't recall. Q. Would you have liked to have been asked for your feedback on how to properly tension the device since you seem pretty sure about how to correctly do it?  MR. GAGE: Object to form. A. Sure. BY MR. FAES: Q. Doctor, will you be offering opinions in this case related to the properties and performance of the TVT mesh?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."  BY MR. FAES:  Q. Would you agree that the surface area of the mesh is one property that affects the safety profile of the mesh?  A. I don't know that that has much bearing on the safety profile, so no.  Q. Do you agree that the tensile strength of the TVT mesh is one property that affects the safety profile of the mesh?  A. No, I think that speaks more to the durability of the mesh.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?  A. I don't recall. Q. Would you have liked to have been asked for your feedback on how to properly tension the device since you seem pretty sure about how to correctly do it?  MR. GAGE: Object to form.  A. Sure.  BY MR. FAES: Q. Doctor, will you be offering opinions in this case related to the properties and performance of the TVT mesh? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."  BY MR. FAES:  Q. Would you agree that the surface area of the mesh is one property that affects the safety profile of the mesh?  A. I don't know that that has much bearing on the safety profile, so no.  Q. Do you agree that the tensile strength of the TVT mesh is one property that affects the safety profile of the mesh?  A. No, I think that speaks more to the durability of the mesh.  Q. Well, would you agree that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?  A. I don't recall. Q. Would you have liked to have been asked for your feedback on how to properly tension the device since you seem pretty sure about how to correctly do it?  MR. GAGE: Object to form.  A. Sure.  BY MR. FAES: Q. Doctor, will you be offering opinions in this case related to the properties and performance of the TVT mesh?  A. Yes. Q. Would you agree that the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."  BY MR. FAES:  Q. Would you agree that the surface area of the mesh is one property that affects the safety profile of the mesh?  A. I don't know that that has much bearing on the safety profile, so no.  Q. Do you agree that the tensile strength of the TVT mesh is one property that affects the safety profile of the mesh?  A. No, I think that speaks more to the durability of the mesh.  Q. Well, would you agree that tensile strength of the mesh is one property
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Abbrevo device after it was launched?  A. I don't know about that. Q. Did they ever ask for your feedback on how to properly tension the Abbrevo device?  A. I don't recall. Q. Did they ever ask for your feedback on how to properly tension any of the TVT devices?  A. I don't recall. Q. Would you have liked to have been asked for your feedback on how to properly tension the device since you seem pretty sure about how to correctly do it?  MR. GAGE: Object to form.  A. Sure.  BY MR. FAES: Q. Doctor, will you be offering opinions in this case related to the properties and performance of the TVT mesh? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it's too tight, so yes.  Q. Would you agree that stiffness of the TVT mesh is one of the properties that may affect the safety profile of the mesh?  A. Yes. It has to be flexible, not too stiff, and that's what we see with the TVT.  MR. FAES: Object and move to strike after the word "stiff."  BY MR. FAES:  Q. Would you agree that the surface area of the mesh is one property that affects the safety profile of the mesh?  A. I don't know that that has much bearing on the safety profile, so no.  Q. Do you agree that the tensile strength of the TVT mesh is one property that affects the safety profile of the mesh?  A. No, I think that speaks more to the durability of the mesh.  Q. Well, would you agree that

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	Page 62		Page 64
1	Q. Would you agree that surface	1	company researches a medical device
2	area of the mesh is one property that affects	2	company researches before a product is
3	the efficacy of the mesh?	3	designed?
4	A. Yes, I can agree with that,	4	MR. GAGE: Object to form.
5	because if it were really narrow or really	5	A. I have ideas and conjectures,
6	wide, it could change the efficacy.	6	but I don't know specifically what they
7	Q. Would you agree that if the	7	what they do.
8	mesh were too narrow to the point of a	8	BY MR. FAES:
9	string, it could affect the efficacy or cause	9	Q. Would you agree that surgery
10	urinary retention?	10	rates for stress urinary incontinence have
11	A. Yes, if it were too tight.	11	increased since the introduction of the TVT?
12	Q. Doctor, do you know what the	12	A. That surgery rates have
13	standard is that a manufacturer should follow	13	increased? I think so, yes.
14	when designing mesh products?	14	Q. Have your surgery rates
15	MR. GAGE: Object to form.	15	increased following the adoption of the TVT?
16	A. Whose standard are you	16	A. Well, it's hard to say with me
17	referring to?	17	because I came out of training right when it
18	BY MR. FAES:	18	was released. So I've
19	Q. I'm just asking, do you know of	19	Q. So you don't have
20	any standards that manufacturers should or	20	A only really practiced in the
21	must follow in designing mesh products?	21	era of TVT.
22	A. Not that I'm aware of.	22	Q. So you can't really answer that
23	Q. Are you familiar with ISO	23	because you don't have a really good
24	standards at all?	24	before-and-after picture?
	P (2		
	Page 63		Page 65
1	A. Not that I can remember.	1	Page 65 A. Correct.
1 2	A. Not that I can remember.	1 2	A. Correct.
	<ul><li>A. Not that I can remember.</li><li>Q. Do you know what</li></ul>		<ul><li>A. Correct.</li><li>Q. You can answer if you know. Do</li></ul>
2	<ul><li>A. Not that I can remember.</li><li>Q. Do you know what responsibilities a manufacturer holds in</li></ul>	2	A. Correct. Q. You can answer if you know. Do you know if Dr. Anhalt's surgery rates
2 3	<ul><li>A. Not that I can remember.</li><li>Q. Do you know what</li></ul>	2 3	<ul><li>A. Correct.</li><li>Q. You can answer if you know. Do</li></ul>
2 3 4	A. Not that I can remember. Q. Do you know what responsibilities a manufacturer holds in designing mesh products?	2 3 4	A. Correct. Q. You can answer if you know. Do you know if Dr. Anhalt's surgery rates increased following the adoption of TVT?
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17 (Pages 62 to 65)

	Page 66		Page 68
1	BY MR. FAES:	1	FURTHER EXAMINATION
2	Q. Doctor, we're back on the	2	BY MR. FAES:
3	record. Are you ready to proceed?	3	Q. Doctor, when you serve as an
4	A. Yes.	4	expert, you want to be fair and impartial,
5	Q. Doctor, do you know who Schlomo	5	right?
6	Raz is?	6	A. Correct.
7	A. Yes.	7	Q. In order to be fair and
8	Q. Would you agree that he's one	8	impartial, you want to review the evidence
9	of the most respected pelvic floor surgeons	9	and get all sides of the story, right?
10	in the world?	10	A. Correct.
11	A. Yes.	11	MR. FAES: No further
12	Q. Would you agree that he's an	12	questions.
13	expert in treating mesh complications?	13	MR. GAGE: So we're done.
14	A. Probably at this point, yes.	14	(Deposition Concluded At
15	Q. Would you agree that he has	15	12:22 p.m.)
16	more experience and expertise in pelvic floor	16	00o
17	surgery than you do?	17	000
18	A. He's definitely got more	18	
19	experience, yes.	19	
20	MR. FAES: No further	20	
21	questions.	21	
22	EXAMINATION	22	
23	BY MR. GAGE:	23	
24	Q. Dr. Pramudji, do you recall	24	
	Page 67		Page 69
		1	CERTIFICATE
1	being asked about whether you had reviewed	2	I, MICHEAL A. JOHNSON, Registered
2	certain depositions of Ethicon employees?	3	Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary
3	A. Yes.	4	Public, do hereby certify that prior to the commencement of the examination, CHRISTINA
4	Q. And in response to one of those	5	PRAMUDJI, M.D. was duly sworn by me to testify to the truth, the whole truth and
5	questions, you said, the fact whether you	6	nothing but the truth.
6 7	reviewed one or more of those depositions was	7	I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the
	not going to trump your experience and the		testimony as taken stenographically by and
8	literature. Do you recall that response?	8	before me at the time, place and on the date hereinbefore set forth, to the best of my
9	A. Yes.	9 10	ability.  I DO FURTHER CERTIFY that pursuant
11	Q. What does that mean?	11	to FRCP Rule 30, signature of the witness was not requested by the witness or other party
	A. That means that the body of	12	before the conclusion of the deposition.
1 つ	literature and my even evenemence in even -		
12	literature and my own experience in over a		I DO FURTHER CERTIFY that I am
13	thousand patients is more important to my	13	neither a relative nor employee nor attorney nor counsel of any of the parties to this
13 14	thousand patients is more important to my opinions than the opinions of company	13 14	neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and
13 14 15	thousand patients is more important to my opinions than the opinions of company employees.	13	neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor
13 14 15 16	thousand patients is more important to my opinions than the opinions of company employees.  Q. Why is that?	13 14 15	neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the
13 14 15 16 17	thousand patients is more important to my opinions than the opinions of company employees.  Q. Why is that?  A. Because that is the actual	13 14 15 16 17	neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.
13 14 15 16 17 18	thousand patients is more important to my opinions than the opinions of company employees.  Q. Why is that?  A. Because that is the actual clinical outcome, actually what is happening	13 14 15 16 17	neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.  MICHEAL A. JOHNSON, RDR, CRR NCRA Registered Diplomate Reporter
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	Page 70		Page 7	2
1	INSTRUCTIONS TO WITNESS	1	ACKNOWLEDGMENT OF DEPONENT	
2	INSTRUCTIONS TO WITNESS	2	ACKNOWLEDGMENT OF DEFONENT	
	Dl d didi	3		
3	Please read your deposition over	4	I, CHRISTINA PRAMUDJI, M.D., do	
4	carefully and make any necessary corrections.	here	by certify that I have read the foregoing	
5	You should state the reason in the		es and that the same is a correct	
6	appropriate space on the errata sheet for any		scription of the answers given by me to	
7	corrections that are made.		questions therein propounded, except for corrections or changes in form or	
8	After doing so, please sign the		stance, if any, noted in the attached	
9	errata sheet and date it.		ita Sheet.	
10	You are signing same subject to	8	and Sheet.	
11	the changes you have noted on the errata	9		
12	sheet, which will be attached to your	10		
13	deposition.	11		
14	-	12		
	It is imperative that you return		RISTINA PRAMUDJI, M.D. DATE	
15	the original errata sheet to the deposing	13		
16	attorney within thirty (30) days of receipt	14 15 <b>Su</b> b	scribed and sworn to before me this	
17	of the deposition transcript by you. If you			
18	fail to do so, the deposition transcript may	17 My	day of, 20 commission expires:	
19	be deemed to be accurate and may be used in	18	ediministron expires.	
20	court.	19		
21		20 Not	ary Public	
22		21		
23		22		
24		23 24		
		24		
	Dago 71		Dago 7	2
	Page 71		Page 7	3
1	ERRATA	1	Page 7 LAWYER'S NOTES	3
1 2		1 2		3
	ERRATA	2		3
2	ERRATA	2	LAWYER'S NOTES	3
2 3	ERRATA PAGE LINE CHANGE	2 3 PA	LAWYER'S NOTES	3
2 3 4	ERRATA PAGE LINE CHANGE  REASON:	2 3 PAG 4	LAWYER'S NOTES	
2 3 4 5	ERRATA PAGE LINE CHANGEREASON:	2 3 PA0 4 5	LAWYER'S NOTES	
2 3 4 5 6	ERRATA PAGE LINE CHANGE  REASON:  REASON:	2 3 PAC 4 5 6	LAWYER'S NOTES	_ _ _ _
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